OCT 2 3 2000

SECTION 6
510(k) Summary

6.0 510(k) Summary: K 001741

This summary of the 510(k) safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 C.F.R. 807.92.

6.1 Submitter of this premarket notification is:

Radionics, A Division of Tyco Healthcare Group LP
22 Terry Avenue
Burlington, MA 01803
Tel.: (781) 272-1233
Fax: (781) 272-2428

Contact: Kristine Canavan
Senior Regulatory Associate

This summary was prepared on September 14, 2000.

6.2 **Proprietary Name(s):**

6.2.1 Radionics RF Disc Catheter Electrode System
6.2.2 Radionics RFG-3CPlus RF Lesion Generator

6.3 **Classification(s):**

6.3.1 21 CFR 878.4400: Electrosurgical Cutting and Coagulation Device and Accessories
6.3.2 21 CFR 882.4400: Radiofrequency Lesion Generator

6.4 **Predicate Device(s):**

6.4.1 Oratech SpineCATH Intradiscal Catheter (K974464)
6.4.2 Radionics RFG-3CPlus RF Lesion Generator (K982489)

6.5 **Description:**

Radionics RF Disc Catheter Electrode System is designed to deliver controlled RF energy to the annular disc space. The Radionics RF Disc Catheter Electrode System is comprised of an introducer system and a catheter electrode, a Radionics RFG-3CPlus RF lesion generator, and a Radionics thermocouple adapter system (TCA-2). The introducer system consists of 20cm, 15° arced tip cannula (insulated) and stylet. The catheter electrode is 25cm, and can extend beyond the cannula up to 5cm; proximal marker depth bands, at 1cm intervals, reference the active tip length. The catheter electrode has a pre-bent tip to facilitate placement along the annular nucleus/tissue interface and has an integral thermocouple to measures tissue temperature during treatment and to lesion the tissue. The RF Disc Catheter Electrode System is used with Radionics RFG-3CPlus RF lesion generator to measure the impedance of the tissue to verify proper placement of the devices. Radionics TCA-2 is used to monitor the posterior outer annular (POA) tissue temperature. The TCA-2 can be used with any commercially available Radionics temperature monitoring electrodes.

6.6 **Intended Use:**

6.6.1 Radionics RF Disc Catheter Electrode System:

The Radionics RF Disc Catheter Electrode System, in combination with Radionics RFG-3CPlus and RFG-3CF RF lesion generators, is indicated for the coagulation and decompression of disc material to treat symptomatic patients with annular disruption of contained herniated discs.

6.6.2 Radionics RFG-3CPlus RF Lesion Generator:

The Radionics RFG-3CPlus RF lesion generator is intended to create lesions in nervous tissue, and for the coagulation and decompression of disc material to treat symptomatic patients with annular disruption of contained herniated discs.

6.7 **Substantial Equivalence:**

The Radionics RF Disc Catheter Electrode System is substantially equivalent to the Oratech SpineCATH Intradiscal Catheter System. The design, intended use, and application of the Radionics System is similar to that of the Oratech System. Both systems create lesions, based on temperature and time settings of the generator, using RF controlled energy via a catheter electrode.

The modified Radionics RFG-3CPlus RF lesion generator is substantially equivalent to the Radionics RFG-3CPlus RF lesion generators. The physical and code modifications do not alter the original design, intent, or function of the generator, and is only enabled when using the Radionics RF Disc Catheter Electrode.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 23 2000

Ms. Christine Canavan
Senior Regulatory Associate
Radionics, Inc.
22 Terry Avenue
Burlington, Massachusetts 01803

Re: K001741
Trade Name: Radionics RF Disc Catheter Electrode System
Regulatory Class: II
Product Code: HRX, GEI
Dated: September 14, 2000
Received: September 15, 2000

Dear Ms. Canavan:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
~~Division of General~~, Restorative
and Neurological Devices
~~Office of Device~~ Evaluation
Center for Devices and
~~Radiological~~ Health

Enclosure

SECTION 2
ODE INDICATIONS STATEMENT

510(k) Number (if known): K001741

Device Name: **Radionics RF Disc Catheter Electrode System**

Indications for use:

The Radionics RF Disc Catheter Electrode System, in combination with Radionics RFG-3CPlus RF lesion generator, is intended for the coagulation and decompression of disc material to treat symptomatic patients with annular disruption of contained herniated discs.

510(k) Number (if known): K001741

Device Name: **Radionics RFG-3CPlus RF Lesion Generator**

Indications for use:

The Radionics RFG-3CPlus RF lesion generator is intended to create lesions in nervous tissue, and for the coagulation and decompression of disc material to treat symptomatic patients with annular disruption of contained herniated discs.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

PRESCRIPTION USE ✓ OR Over-The-Counter Use ___

(Per 21 CFR 801.109

(Optional Format 1-2-96)

for Mark N Melkerson

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K001741